REMARKS

The Office Action mailed February 11, 2004, has been received and reviewed. Claims 1, 10, 33 and 34 are pending. Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement and written description commensurate with the scope of the claims. Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being ambiguous and indefinite. Claims 1, 10 and 33 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Huang *et al.* Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Huang *et al.* in view of Remington's Pharmaceutical Sciences. Reconsideration is respectfully requested.

Interview:

The applicants thank the Examiner for the courtesy of the interview conducted March 25, 2004. As agreed to at the interview the claims have been amended so as to overcome the rejections under 35 U.S.C. § 112, first and second paragraphs, *i.e.*, by including the language recited in the Interview Summary "a pharmaceutical composition consisting of a peptide consisting of an amino acid of SEQ ID NO:1."

Substitute Specification:

A substitute specification is submitted herewith to correct typographical errors in the specification. The substitute specification is believed to contain no new matter. In accordance with 37 C.F.R. § 1.125 a clean copy and a marked up version showing all of the changes made to the specification are provided as Appendix A and B, respectively.

Rejections under 35 U.S.C. § 112, first paragraph:

A. Enablement:

Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement commensurate with the scope of the claims. The Office Action states that the specification **is** enabling for "(1) a pharmaceutical composition consisting of a

peptide consisting of SEQ ID NO:1 and a pharmaceutically acceptable carrier or excipient for treating bronchial constriction ..." (page 2 of the Office Action). The Office goes on to indicate that the treatment of "*any* disease [is not enabled] because there is insufficient guidance as to the structure of a 'peptide of SEQ ID NO:1' ... since the length of the peptide is ambiguous" (page 3 of the Office Action). The applicants respectfully disagree, since the claims already contain the transition phrase "consisting of." However, the applicants have amended the claim as suggested and agreed to at the interview. Independent claims 1 and 10 now expressly recite the Office suggests in the Office Action (page 3 of the Office Action; and as agreed in the interview conducted March 25, 2004).

Moreover, the Office has indicated that the language of the present claims is enabled and has sufficient written description. Specifically, "a pharmaceutical composition consisting of SEQ ID NO:1 and a pharmaceutical[ly] acceptable carrier ... overcome[s] the ... enablement and written description [rejection]" (the Interview Summary, Paper 14).

As discussed at the interview "when a compound or composition claimed is not limited by a recited use, any enabled use [for example, treatment of bronchial constriction] that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use" (MPEP §2164.01(c)) (emphasis added). Therefore, claims 1, 10, 33, and 34 are enabled as acknowledged by the Examiner's statement "that the claimed pharmaceutical composition is effective for ... bronchial constriction" (page 4 of the Office Action). In particular, claims 33 and 34 encompass precisely what has been acknowledged as enabled.

Therefore, in light of the instant specification's disclosure regarding the peptide's effect on the binding of Ig LC to mast cells and diseases having as a symptom free light chain, which is a part of the T-cell factor responsible for sensitizing mast cells, the claims are enabled (*see*, for example, page 4, line 35 to page 5, line 15; and page 2, lines 15-18 of the specification). In addition, claim 10 expressly recites free light chain immunoglobulin levels that characterize the disease.

The Office Action also indicates that the mouse models used in the specification may not

be appropriate for all autoimmune diseases (page 3 of the Office Action). The Office cites Van Noort *et al.* for the proposition that autoimmune diseases can be species and model-dependent (page 3 of the Office Action). Autoimmune diseases can be antigen specific (*see*, for example, Van Noort *et al.* at 128), and each model has its own characteristics, due to the interaction of the host immune system and the experimental antigen (for example, *see*, Van Noort *et al.* at 167-168). However, such reasoning merely indicates that disease models are influenced by a number of factors, but does not contraindicate the applicability of the mouse models used in the Examples. In the absence of reasoning showing the inapplicability of the models used in the application, they should be accepted as correlating to the method of use (MPEP § 2164.02; and *In re Brana*, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995)). As discussed at the interview, the present claims are not directed to a method of using the compound, therefore, the correlation between the *in vivo* model and the method of using the compound should not apply.

Finally, the Office notes in the rejection under 35 U.S.C. § 103(a) that the concentration of peptide, such as 200 μg, is within the purview of one of ordinary skill in the art. In view of this acknowledgment by the Office, stating that the specification is only enabled for a dosage of 200 μg is inconsistent with the rejection under 35 U.S.C. § 103(a). Furthermore, other dosages are disclosed in the instant specification, for example, 250 μg/ml, and 500 μg/ml (*see*, page 8, lines 1-12 of the instant specification). Applicants, respectfully submit that determining an effective dosage is within the purview of a person of ordinary skill in the art.

Because the length of the peptide of SEQ ID NO:1 is definite and clearly defined by the claims, reconsideration and withdrawal of the rejection is respectfully requested.

B. Written Description:

Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly the recitation of a "pharmaceutical composition consisting of a peptide **of** SEQ ID NO:1" is ambiguous and indefinite (claim 1 (emphasis added); *see also*, page 6 of the Office Action). The amended claims, as acknowledged in the interview conducted March 25, 2004, have sufficient written description.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph:

As discussed herein, the peptide, which is shown in [of] SEQ ID NO:1, makes clear the length of the peptide in the claimed composition. One of ordinary skill in the art can appraise the metes and bounds of the claimed invention. The claimed invention is a pharmaceutical composition consisting of the peptide consisting of an amino acid sequence of SEQ ID NO:1. Therefore, as agreed in the interview (the Interview Summary, Paper 14), there is no ambiguity regarding the length of the peptide with respect to the amended claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(b):

Claims 1, 10 and 33 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Huang *et al.* As discussed in the previous response to the Office, Huang *et al.* does not disclose a pharmaceutical composition consisting of a peptide of sequence AHWSGHCCL (SEQ ID NO:1) and a pharmaceutically acceptable carrier or diluent. Using closed "consisting of" language excludes non-pharmaceutically acceptable carriers and excipients, as well as additional elements which would change the properties of the invention. At most, Huang *et al.* discloses the peptide of SEQ ID NO:1 together with immunoglobulin light chain (LC). LC is not the peptide of SEQ ID NO:1, nor is it a pharmaceutically acceptable carrier or excipient. Furthermore, inclusion of the immunoglobulin light chain (Ig LC) is materially different from the present invention. The presently claimed invention is directed to the peptide of SEQ ID NO:1, which is used to interrupt the binding of the Ig LC to mast cells. Hence, adding more of the Ig LC, which the claimed compound is to interact with and prevent from binding to a mast cell, is contrary to the claimed invention. Because the peptide plus additional Ig LC, as disclosed in Huang *et al.*, is contrary to the claimed invention, the reference is materially different from the claimed compound alone and can not anticipate the claimed invention. As a result, Huang *et al.* fails to teach or suggest a pharmaceutical composition

consisting of a peptide consisting of an amino acid sequence of SEQ ID NO:1 and a pharmaceutical carrier or excipient. Because the reference teaches SEQ ID NO:1 **with** Ig LC, and Ig LC is precisely what the compound is used to inhibit, the anticipation rejection necessarily fails.

Reconsideration and withdrawal of the rejection is thus respectfully requested.

Rejections under 35 U.S.C. § 103(a):

As discussed herein and at the interview, Huang *et al.* does not teach or suggest the claimed invention. Huang *et al.* discloses the peptide of SEQ ID NO:1 together with Ig LC, which is materially different from the claimed composition. Moreover, Huang *et al.* provides no motivation to make or use the peptide as a pharmaceutical composition. In particular, Huang *et al.* states that the light chain binding site on THP will "help produce strategies that inhibit interaction of LCs with THP ..." (Huang *et al.* at page 736, first column; emphasis added). Thus, Huang *et al.* merely suggests a possible future research tool directed at finding inhibitors of the interaction between an LC and THP. Huang *et al.* does not provide motivation to a person of ordinary skill in the art to make or use a peptide as a pharmaceutical composition to induce an interaction with the LC.

Gennaro *et al.* does not teach or suggest a pharmaceutical comprising the peptide of SEQ ID NO:1 or a composition that interacts with the LC. Therefore, this reference does not supply the missing elements and does not render the claims obvious in light of Haung *et al.*

Reconsideration and withdrawal of the rejection is respectfully requested.

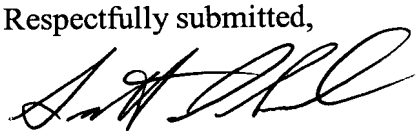
CONCLUSION

The application is to be amended as previously set forth in an effort to conform more closely to U.S. practice. All amendments are made without prejudice or disclaimer.

In view of the foregoing, claims 1, 10, 33 and 34 should be in condition for allowance, and early notification of such is respectfully requested. If questions exist after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the number given below.

The applicants request entry of the amendments as set forth herein and in the Appendices attached hereto. No new matter has been added.

Respectfully submitted,



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